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## Complications in the first 5 years following cataract surgery in infants with and without intraocular lens implantation in the Infant Aphakia Treatment Study

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### Introduction

Implantation of an intraocular lens (IOL) at the time of cataract surgery is commonly done for most patients above one year of age. (1) There is considerably less consensus on the proper role of IOL implantation in infants. (2–7) Theoretical advantages of primary IOL implantation at the time of cataract surgery in infants include having a constant, albeit partial, optical correction during the early years of visual development, the ability to place the IOL within the capsular bag and the avoidance of contact lens use with the associated cost and effort required of the child's caregivers. (8, 9) Advantages of leaving the baby aphakic and visually rehabilitating the eye with a contact lens include the ability to change the contact lens power as needed to keep up with the rapidly growing eye's refractive needs, not subjecting the baby to the increased rate of complications and subsequent need for additional surgeries associated with IOL implantation and not requiring spectacle wear during the first few years of life. (10–18)

The Infant Aphakic Treatment study is a multicenter, randomized clinical trial that compares the use of primary IOL implantation with spectacle correction of residual hyperopia to the

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#### Contributions to Authors

- a. Design and conduct of study (DAP, MJL,EGB,MEW,SRL)
- b. Collection, Management, analysis and interpretation of data (DAP, MJL,EGB,MEW,SRL)
- c. Preparation, review and approval of manuscript (DAP, MJL,EGB,MEW,SRL)

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correction of aphakia with a contact lens after cataract surgery performed in infants with a unilateral congenital cataract between 1 and 7 months of age. (19) The study found no significant difference in grating visual acuity between the two groups at one year of age, but there was a significantly higher rate of complications, adverse events and need for additional intraocular surgeries in the IOL group at that time. (4) The optotype visual acuities obtained at 4.5 years in the IATS were recently reported. (20) Consistent with the one year grating acuities, the 4.5 year optotype acuities showed no significant difference between the two study groups.

The purpose of this report is to examine in greater depth the rate and character of adverse events and additional intraocular surgeries required by age five years. This analysis will hopefully assist in formulating recommendations for the use of IOL implantation in infants.

## Methods

The study design (multi-center randomized clinical trial), surgical techniques, follow up schedule and patient characteristics at baseline, as well as the clinical findings at one year of age have been reported in detail previously and are only summarized here. (4, 19) This study was approved by the Institutional Review Boards of all 12 participating institutions and was in compliance with the Health Insurance Portability and Accountability Act. Informed consent was obtained from all parents or guardians. The off-label research use of the Acrysof SN60AT and MA60AC IOLs (Alcon Laboratories, Fort Worth, Texas) was covered by US Food and Drug Administration investigational device exemption # G020021. The trial is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier- NCT00212134).

## Study Design

The main inclusion criteria were a visually significant congenital cataract ( $> 3$  mm central opacity) in one eye and an age of 28 days to  $<210$  days at the time of cataract surgery. Infants with a unilateral cataract due to persistent fetal vasculature were allowed in the study as long as the persistent fetal vasculature was not associated with visible stretching of the ciliary processes or involvement of the retina or optic nerve.

Infants randomized to the contact lens group underwent a lensectomy and anterior vitrectomy. Infants randomized to the IOL group had the lens contents aspirated followed by the implantation of an AcrySof SN60AT IOL into the capsular bag. In the event that both haptics could not be implanted into the capsular bag, an AcrySof MA60AC IOL was implanted into the ciliary sulcus. The IOL power was calculated based on the Holladay 1 formula targeting a postoperative refractive error of +8 D for infants 4–6 weeks of age and +6 D for infants older than 6 weeks. Following IOL placement, a posterior capsulectomy and an anterior vitrectomy were performed through the pars plana/plicata. When either a pre-existing opening was present, as sometimes occurs with posterior lenticonus defects, or a rent developed intraoperatively in the posterior capsule and in some eyes with mild PFV, the posterior capsulectomy and anterior vitrectomy were performed through the anterior incision prior to IOL implantation.

There were 114 children enrolled in the study with 57 randomized to each treatment group. In years 2–5 following surgery, the patients were examined by an Infant Aphakia Treatment Study certified investigator every 3 months until 4 ½ years of age and then a final exam at age 5 years. One hundred and thirteen patients had a clinical exam at age 5 years (mean, 5.0 years; range, 4.7 – 5.4 years) with an average length of follow-up of 4.8 years (range, 4.4 – 5.3 years) after cataract surgery. One patient in the IOL group was lost to follow-up at age 18 months.

### Adverse Events

IOP was measured using rebound tonometry (ICare Finland, Helsinki, Finland), a Tonopen (Reichert Technologies, Depew, NY) or Goldmann applanation tonometry.

*Glaucoma* was defined as IOP >21 mmHg with one or more of the following anatomical changes: 1) corneal enlargement; 2) asymmetrical progressive myopic shift coupled with enlargement of the corneal diameter and/or axial length; 3) increased optic nerve cupping defined as an increase of 0.2 in the cup-to-disc ratio, or 4) the use of a surgical procedure to lower IOP.

*Glaucoma suspect* was defined as either: 1) two consecutive IOP measurements above 21 mmHg on different dates after topical corticosteroids had been discontinued without any of the anatomical changes listed above; or 2) glaucoma medications were used to control IOP without any of the anatomical changes listed above.

A *corneal ulcer* was defined as a corneal epithelial defect with an associated corneal infiltrate whereas a *corneal abrasion* was defined as a corneal epithelial defect with no infiltrate.

*Lens re proliferation into the visual axis* was defined as lens regrowth extending into the pupillary space and interfering with vision. Other adverse events encountered that were deemed to not require definition include: pupillary membrane, corectopia, vitreous hemorrhage, hyphema, retained cortex, retinal detachment, corneal edema, wound leak, IOL capture, endophthalmitis and phthisis bulbi.

### Statistical Methods

The percentage of patients experiencing one or more adverse events was compared between the treatment groups using Fisher's exact test. The analysis was done for the first year following cataract surgery, for the follow-up period after the first year and over the entire follow-up period. The same approach was used to compare the percentage of patients undergoing one or more additional ocular surgical procedures. The rate for the number of adverse events per patient-year of follow-up was compared between the treatment groups using the exact binomial test for comparing two Poisson means. This analysis was done for the first postoperative year and for the follow-up period after the first year. This same method was also used to compare the rate of ocular surgery procedures per patient-year of follow-up.

## Results

### Adverse Events

Table 1 shows the adverse events that occurred in each treatment group during the first year after cataract surgery as previously reported (11) as well as those that occurred in years 2 thru 5 of follow-up.

During the first year after cataract surgery a lower percentage of contact lens patients experienced one or more adverse events compared to IOL patients (contact lens: 15 (26%), IOL: 44 (77%),  $p < 0.0001$ ). After the first year there was a trend for a higher percentage of contact lens patients to experience an adverse event (contact lens: 24 (42%), IOL: 14 (25%),  $p = 0.073$ ). Over the entire follow-up period, the proportion of contact lens patients experiencing an adverse event was lower than the IOL patients (contact lens: 32 (56%), IOL: 46 (81%),  $p = 0.008$ ).

Table 1 further shows the number of patients who had at least one adverse event. For the majority, there was one event per patient. The exceptions are the following: In the contact lens group there were 4 contact lens related adverse events among 3 patients in the first year and 14 events among 7 patients after the first year for a total of 18 events among 10 patients. In the IOL group, during the first year, there were multiple instances of the following adverse events: lens repopulation – 27 among 23 patients; pupillary membrane – 20 among 16 patients; corectopia – 15 among 13 patients; and retained cortex – 4 among 3 patients. After the first year: pupillary membrane – 5 among 3 patients and hyphema – 2 in 1 patient.

During the first year, in the contact lens group there were 22 adverse events among 15 patients and in the IOL group there were 88 events among 44 patients. When translated to an annual rate, the number of adverse events per year of follow-up was significantly lower in the contact lens group compared to the IOL group (contact lens: 0.4, IOL: 1.6,  $p < 0.0001$ ). After the first year, there were 33 events among 24 patients in the contact lens group and 21 events among 14 patients in the IOL group, which yielded rates that were not significantly different in the two groups (contact lens: 0.2, IOL: 0.1,  $p = 0.15$ ).

Compared to the first postoperative year in which there was a total of 110 adverse events (contact lens: 22, IOL: 88), there were only 54 adverse events (contact lens: 33, IOL: 21) in years 2–5. A large majority of the adverse events during the five years of follow up in the IOL group occurred in the first year (88 of 108, 81%). Conversely, more adverse events in the contact lens group developed in years 2–5 than occurred in the first year (33 of 54, 61%).

Thirty of the 33 adverse events that developed in the contact lens group in years 2–5 were glaucoma related ( $n=16$ ) or contact lens related ( $n=14$ ). Seventeen of the 21 adverse events that developed in the IOL group in years 2–5 were visual axis related ( $n=10$ ) or glaucoma related ( $n=7$ ).

### Additional Intra-ocular surgeries

As shown in Table 2, there were more patients with unplanned intraocular procedures in the IOL group ( $n=8$ ) than the contact lens group ( $n=4$ ) during post-operative years 2–5.

IOL group- 8 patients had procedures to clear visual axis opacities, 2 had glaucoma surgery and 2 had an IOL exchange

Contact lens group- 3 patients had procedures to clear visual axis opacities and 1 had glaucoma surgery.

In addition, 3 patients in the contact lens group underwent elective secondary IOL implant because of their inability to wear a contact lens successfully.

During the first year after cataract surgery a lower percentage of contact lens patients had one or more additional surgical procedures compared to IOL patients (contact lens: 7 (12%), IOL: 36 (63%),  $p < 0.0001$ ). After the first year the percentage of patients having surgery did not differ significantly between the groups (contact lens: 4 (7%), IOL: 8 (14%),  $p = 0.36$ ). Over the entire follow-up period, a lower percentage of contact lens patients had additional intraocular surgery (contact lens: 9 (16%), IOL: 41 (72%),  $p < 0.0001$ ).

For most of the procedures listed in Table 2, there was one procedure per patient. The exceptions are the following: In the contact lens group, during the first year there were 8 procedures involving clearing visual axis opacities among 6 patients and 3 procedures for repairing a retinal detachment among 2 patients. In the IOL group, during the first year, there were 44 procedures involving clearing visual axis opacities among 34 patients and after the first year there were 10 similar procedures among 8 patients.

During the first year, in the contact lens group there were 13 surgical procedures among 7 patients and in the IOL group there were 52 procedures among 36 patients. The corresponding rate of procedures per year was significantly lower in the contact lens group (contact lens: 0.2, IOL: 0.9,  $p < 0.0001$ ). After the first year, there were 4 procedures among 4 patients in the contact lens group and 14 procedures among 8 patients in the IOL group, resulting in a lower rate in the contact lens group (contact lens: 0.02, IOL: 0.07,  $p = 0.029$ ). As with the first year procedures, the most common unplanned additional intraocular procedure was done to clear visual axis opacity (contact lens group,  $n=3$  (75%); IOL group,  $n=10$  (71%)). Of the total of five other intraocular procedures, 3 were for glaucoma (IOL group,  $n=2$ ) and 2 were IOL exchanges.

## Discussion

As previously reported, at one year of age the patients in the IOL group had experienced more intraoperative complications (28% vs. 11%,  $p=.031$ ), postoperative adverse events (77% vs 25%,  $p< .0001$ ) and required more additional intraocular surgeries (63% vs 12%,  $p< .0001$ ) than did babies who were left aphakic. (11) The most common adverse event was visual axis opacification and the most common additional intraocular surgery was a clearing of visual axis opacification.

The numbers of adverse events that developed in years 2–5 of follow-up were relatively few ( $n=54$ ) compared to the first postoperative year ( $n=110$ ). Nearly half of the 54 adverse events ( $n=23$ ) were related to glaucoma. Ten patients were diagnosed with glaucoma and 13 became glaucoma suspects during years 2–5. This was in addition to 10 patients who had been diagnosed with glaucoma during the first year. At five years, a total of 20 children in

the contact lens group had been diagnosed with glaucoma or labeled a glaucoma suspect versus a total of 16 children in the IOL group, an insignificant difference. The expectation is that the numbers of children diagnosed with glaucoma will continue to rise with time. Glaucoma is probably the most important long term issue facing patients who undergo cataract surgery in the first six months of life (this topic will be covered in more detail in a subsequent publication from this study).

Another area where we can expect to see the numbers of adverse events rise with time will be contact lens related events. There were 4 such events in the first year and 14 in the subsequent four years. As long as children continue to wear contact lenses, more contact lens related adverse events are likely to occur. Fortunately, to date, none of the contact lens related events, which include two corneal ulcers, have resulted in loss of vision.

In the IOL group, 3 patients to date have undergone IOL exchange because of an excessive myopic shift. It can be expected that this number may rise over the next decade of continued growth of these young eyes with associated change in refractive error.

Only one eye of the 114 eyes in the study lost vision completely (NLP). This was a patient in the contact lens group that developed a retinal detachment in the early postoperative period and the eye became phthisical. A second child, also in the contact lens group, developed endophthalmitis in the early postoperative period and had only LP vision at 4.5 years.

Ultimately, the clinician treating infants with congenital cataracts would like to know if implantation of an IOL at the time of cataract surgery is advisable. While there is no clear-cut answer for all patients, the data favor delaying IOL implantation until the child is older for families that can reasonably manage contact lens care and expense. Delaying IOL implantation until later years after most of the growth in axial length has occurred also obviates some of the unpredictability in selecting an appropriate IOL power for implantation.

However for other families, for whom contact lens care may be burdensome, the answer is not so clear. While there is no advantage in the visual outcome at age 4.5 years if an IOL is implanted (20), there are other advantages to primary IOL implantation. The most obvious to the families involved is that it is not necessary for the baby to wear a contact lens. The extent to which this is an advantage will differ among patients and families. Some caregivers can become quite adept at handling the contact lens and some babies adapt to them well, but obviating this chore would likely be welcomed by most. In some family situations, the effort required to successfully wear an aphakic contact lens in a young child presents an insurmountable barrier. Additionally, the cost associated with many years of contact lens wear, especially in cases where the lens is frequently lost, is a significant burden. Notably, the financial barrier to contact lens wear was removed for the families in the Infant Aphakia Treatment Study because all associated contact lens expenses were borne by the study.

Another, at least theoretic, advantage to primary IOL implantation is that the IOL can be more reliably placed within the capsular bag at the time of the original surgery than as a secondary procedure (21). Although the long term risk of placing an IOL in the sulcus of a

baby in terms of future IOL decentration or uveitis related complications is unknown, it is likely that capsular bag fixation will be more secure and less prone to adverse events over the long life span of these babies.

These real and potential advantages need to be weighed against the higher rate of complications, adverse events and need for additional intraocular surgeries associated with primary IOL placement in infancy. At five years of age, the total number of additional unplanned intraocular surgeries clearly favor the contact lens group – there were 66 procedures in the IOL group versus 17 in the CL contact lens group. However it is important to realize that the two groups are not equivalent- the contact lens group is aphakic and the IOL patients are pseudophakic. Many of children in the aphakic group will opt to have a secondary IOL electively placed in future years and these secondary implant procedures may themselves be associated with additional complications. On the other hand, an unknown number of children in the pseudophakic group will likely opt for an IOL exchange to manage unacceptably high myopic refractive errors that develop with future axial length growth. In sum, these anticipated additional intraocular surgeries will likely bring the total number of surgeries for the two groups closer together.

The aphakic patients in the Infant Aphakia Treatment Study were discouraged from having a secondary IOL implanted during the five years of the study, but despite extensive efforts by study investigators and coordinators to sustain contact lens wear in all patients, three patients were declared contact lens failures and a secondary IOL was implanted prior to five years of age. In the pseudophakic group, a similar effort was made to sustain spectacle wear for residual refractive error. Despite this effort, three patients who developed highly myopic refractive errors as the axial length of the eye increased underwent IOL exchange prior to five years of age.

Another area besides contact lens and glasses compliance where the results found in this study may be difficult to duplicate in the real world is in the numbers of complications, adverse events and additional intraocular surgeries. The numbers of these in this study were significant, but they may represent a best case scenario. All surgeons participating in the study were highly experienced pediatric cataract/IOL surgeons. All were required to submit surgical videos before they were certified to participate that documented their ability to perform the surgical procedures mandated by the study protocol on infants similar to the ones to be enrolled in the study. It is possible that the complication rate of surgeons less experienced with the particular challenges of cataract/IOL surgery on infant eyes would be even higher than that encountered in this study.

In conclusion, compared to infants with no IOL, patients treated with primary IOL implantation prior to 7 months of age had more adverse events and required more additional intraocular surgeries over the first five years following surgery for unilateral congenital cataract, with most occurring during the first postoperative year. While there was no visual benefit demonstrated at 5 years of age and an increased risk of adverse events and additional intraocular surgeries associated with primary IOL implantation in early infancy, there are other factors that could influence the decision whether to implant an IOL in a particular



baby. We suggest that surgeons continue to exercise caution when considering IOL implantation in the management of congenital cataract in the first 7 months of life.

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## Appendix: The Infant Aphakia Treatment Study Group

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Table 1

Number of Adverse Events by Treatment Group in the Infant Aphakia Treatment Study

Adverse Event	Treatment											
	CL (57 Patients)						IOL (57 Patients)					
	During First Post-op Year			After First Post-op Year			During First Post-op Year			After First Post-op Year		
	# Ev	# Pat	# Ev	# Pat	# Ev	# Pat (%)	# Ev	# Pat	# Ev	# Pat	# Ev	# Pat (%)
Lens Reproliferation into Visual Axis	1	1	1	1	2	2 (4%)	27	23	1	1	28	23* (40%)
Pupillary Membrane	0	0	2	2	2	2 (4%)	20	16	5	3	25	16† (28%)
Corectopia	1	1	0	0	1	1 (2%)	15	13	4	4	19	16‡ (28%)
Glaucoma	3	3	6	6	9	9 (16%)	7	7	4	4	11	11 (19%)
Glaucoma Suspect	2	2	10	10	11	11 <sup>§</sup> (19%)	3	3	3	3	5	5 <sup>§</sup> (9%)
CL Related AEs <sup>^</sup>	4	3	14	7	18	10 (18%)	0	0	0	0	0	0 (0%)
Vitreous Hemorrhage	2	2	0	0	2	2 (4%)	4	4	1	1	5	5 (9%)
Retinal Hemorrhage	2	2	0	0	2	2 (4%)	3	3	0	0	3	3 (5%)
Hyphema	1	1	0	0	1	1 (2%)	3	3	2	1	5	4 (7%)
Retained Cortex	2	2	0	0	2	2 (4%)	4	3	0	0	4	3 (5%)
Retinal Detachment	2	2	0	0	2	2 (4%)	0	0	0	0	0	0 (0%)
Endophthalmitis	1	1	0	0	1	1 (2%)	0	0	0	0	0	0 (0%)
Phthisis Bulbi	1	1	0	0	1	1 (2%)	0	0	0	0	0	0 (0%)
Corneal Edema >30 days	0	0	0	0	0	0 (0%)	1	1	0	0	1	1 (2%)
Wound Leak/Dehiscence	0	0	0	0	0	0 (0%)	1	1	0	0	1	1 (2%)
IOL Capture	0	0	0	0	0	0 (0%)	0	0	1	1	1	1 (2%)
<b>Total<sup>x</sup></b>	<b>22</b>	<b>15</b>	<b>33</b>	<b>24</b>	<b>54<sup>§</sup></b>	<b>32// (56%)</b>	<b>88</b>	<b>44</b>	<b>21</b>	<b>14</b>	<b>108<sup>§</sup></b>	<b>46<sup>§</sup> (81%)</b>

# Ev = Number of adverse events; # Pat = Number of patients, CL = Contact Lens group, IOL = IOL group, AE = Adverse Event

\* 1 patient had lens reproliferation into the visual axis in both time periods.

† 3 patients had pupillary membrane in both time periods.

‡ 1 patient had corectopia in both time periods.

patient in the CL group and 1 patient in the IOL group changed from glaucoma suspect in the first time period to glaucoma in the second time period.  
§ 1 patient in the CL group had at least 1 adverse event in both time periods.  
// 7 patients in the CL group had at least 1 adverse event in both time periods.  
¶ 12 patients in the IOL group had at least 1 adverse event in both time periods.  
× For number of patients the total refers to the number of patients with at least 1 adverse event.  
^ Contact lens related AE's included corneal abrasions, corneal ulcers and episodes of keratitis

Number of Additional Intraocular Surgical Procedures By Treatment Group in the Infant Aphakia Treatment Study

Table 2

Type of Surgical Procedure <sup>*</sup>	Treatment											
	CL (57 Patients)						IOL (57 Patients)					
	During First Post-op Year		After First Post-op Year		Total		During First Post-op Year		After First Post-op Year		Total	
	# Pro	# Pat	# Pro	# Pat	# Pro	# Pat	# Pro	# Pat	# Pro	# Pat	# Pro	# Pat
Clearing Visual Axis Opacities	8	6	3	3	11	8 <sup>†</sup> (14%)	44	34	10	8	54	39 <sup>†</sup> (68%)
Glaucoma Surgery	1	1	1	1	2	2 (4%)	4	4	2	2	6	5 <sup>‡</sup> (9%)
Repair Retinal Detachment	3	2	0	0	3	2 (4%)	0	0	0	0	0	0 (0%)
Repair Wound Dehiscence	0	0	0	0	0	0 (0%)	1	1	0	0	1	1 (2%)
IOL Exchange	-	-	-	-	-	-	1	1	2	2	3	3 (5%)
Iridectomy/Iridotomy	1	1	0	0	1	1 (2%)	1	1	0	0	1	1 (2%)
Lysis of Vitreous Wick	0	0	0	0	0	0 (0%)	1	1	0	0	1	1 (2%)
<b>Additional Surgical Procedures</b>	13	7	4	4	17	9 <sup>§</sup> (16%)	52	36	14	8	66	41 <sup>§</sup> (72%)

<sup>#</sup> Pro = Number of surgical procedures; # Pat = Number of patients, CL = Contact Lens group, IOL = IOL group

<sup>\*</sup> Multiple surgical procedures could have been done during the same episode. Exam under anesthesia only, secondary IOL, and strabismus surgery only are not included.

<sup>†</sup> 1 CL patient and 3 IOL patients had surgery to clear the visual axis in both time periods.

<sup>‡</sup> 1 IOL patient had glaucoma surgery in both time periods.

<sup>§</sup> 2 CL patients and 3 IOL patients had at least 1 surgical procedure in both time periods.